Turning Cancer Research into Commercial Products



Computerized Nicotine Education for Adolescents

Grant Number: R44CA75866-03

Abbreviated Abstract

This application proposes the development and field testing of an interactive computer program called "Rebels: The Battle for a Smoke free Future." The program is intended to be offered through high schools to assist adolescents in tobacco cessation. Rebels utilizes multimedia technology for teaching cessation related coping skills. In the program, adolescents will be exposed to the short and long term risks of tobacco use, the ingredients in tobacco products, and media influences in tobacco use in an engaging, dramatic manner. Users of the program will receive tailored motivational feedback based on their tobacco use patterns and motivations, which will then be linked to individualized skill-building interventions. Users will receive printouts tailored to their needs and interests. The program will integrate culturally diverse role model stories to impart tobacco information and cessation strategies. In Phase I, interviews, focus groups, and acceptance tests produced a program structure and prototype. In Phase II: (1) Rebels will be completed (2) a validation of computerized tailoring questions will be compared to standard written questionnaires; and (3) the program will be field tested against a control intervention (standard tobacco education videotapes). If Rebels demonstrably enhances reduction or cessation of tobacco use, an extensive national market would be assured.

Primary Investigator

Emil Chiauzzi, Ph.D. Inflexxion, Inc. 320 Needham Street, Suite 100 Newton, MA 02464 (617) 332-6028 Fax: (617) 332-1820

<u>echiauzzi@inflexxion.com</u> Web site: www.inflexxion.com

Dr. Chiauzzi has 20 years of clinical, research, and training experience in the addictions and psychiatric fields. He is currently Vice President of Product Development at Inflexxion in Newton, MA. Prior to his work at Inflexxion, he directed several treatment programs for addicted clients. He has written extensively on relapse prevention and provided strategies for addiction treatment in a variety of clinical settings. His book, Preventing Relapse in the Addictions: A Biopsychosocial Approach, published in 1991, is viewed as a significant contribution to the substance abuse area. He has served as Principal Investigator on numerous federal grants with various branches of the National Institutes of Health, and has completed: Rebels, a teen smoking cessation CD-ROM (NCI); Safe and Sober, an HIV prevention CD-ROM for substance abuse clients (NIAAA); the Health Habits Survey, a brief alcohol intervention CD-ROM for primary care offices; and Facing the Future, a relapse prevention CD-ROM for alcoholic clients (NIAAA); My Student Body: Alcohol, a college high risk drinking prevention website (NIAAA); My Student Body: Tobacco, a college tobacco cessation

Visit the SBIR Product Directory online at http://cancercontrol.cancer.gov/hcirb/sbir

Turning Cancer Research into Commercial Products



website (NCI); Gopp's Galaxy, a tobacco and alcohol prevention CD-ROM for K-2 children (NCI); On the Air, a tobacco cessation CD-ROM for substance abusers (NCI); and Crash Site, an impaired driving prevention CD-ROM for high school students (NIDA). Dr. Chiauzzi authors content for these projects, including multimedia scripts and manuals for providers and participants. Dr. Chiauzzi is the author of Preventing Relapse in the Addictions (Allyn & Bacon) and is the primary author on Time Effective Treatment (Hazelden).

Research Team & Affiliations

Emil Chiauzzi, Ph.D.; Stephen F. Butler, Ph.D.; Don Wertlieb, Ph.D.; Tara Cousineau, Ph.D.; Christopher Gauthier, B.A.; Deborah Trottier, B.S.

Total Budget

\$749,933

Research Objectives

Aim 1: Completion of production of Rebels prototype to be field tested.

Aim 2: Implementation of a comprehensive and extensive field test of the program, with four main goals:

- To validate the assessment questions that tailor the program's components to the individual user.
- To test three primary hypotheses: that students exposed to the Rebels program will improve in the areas of knowledge about nicotine use, attitudes toward quitting (motivation), and reduce tobacco use behavior.
- Test the secondary hypothesis that exposure to the Rebels program will result in higher quit rates than the control condition.
- Assess student acceptance and satisfaction with the Rebels program

Theory/Hypothesis

Primary Hypothesis: Students exposed to the Rebels program will improve in the areas of knowledge about nicotine use, attitudes toward quitting (motivation), and reduce tobacco use behavior.

Secondary Hypothesis: The experiment group exposed to the Rebels program will result in higher quit rates than the control group.

Experimental Design

Efficacy Study: A group of recruited students from 10 different high schools were randomly assigned, within school, to either an experimental group or control group. Students completed baseline assessments and two follow-up assessments, at one- (30 days) and four-months (120 days).

The measures for this project assessed knowledge about tobacco and its consequences (for both tobacco nonusers and users), and for users only: quit rates, reduction rates, and the stage-of-change continuum (Prochaska et al., 1994).

Visit the SBIR Product Directory online at http://cancercontrol.cancer.gov/hcirb/sbir

Turning Cancer Research into Commercial Products



Randomization took place after the baseline assessments and was structured so that there was equal representation of gender and minorities in both the Experimental and Control groups. Experimental participants used Rebels and Control participants viewed four, color videos about nicotine/tobacco designed for adolescents.

User Acceptance and Satisfaction Study: Using the participants from the efficacy study, acceptance will be evaluated using the computer to track how participants are using (or not using) the Rebels program. Satisfaction will be examined by an in-person interview.

Final Sample Size & Study Demographics

High school students were recruited from 10 high schools in Massachusetts and New Hampshire. Both smokers and nonsmokers were recruited, 46.7% self identified as tobacco users that "use tobacco at least once a month" at baseline. Mean age of all participants was 16.7 years, with the youngest participant age being 14 and the oldest being 19. 57% of the sample was female and 38% was non-white.

1% of participants were in 8th grade, 13% were freshmen, 26% were sophomores, 26% were juniors, and 34% were seniors in high school.

Data Collection Methods

Efficacy Study: An Inflexxion research assistant (R.A.) is stationed at each of the high schools. Working with a school liaison to assist in recruitment, the R.A. obtained the assent of participants and informed consent from the parents and students over 18 years old. As the student is entered into the study, a randomization schedule assigns the student to either the Experimental or Control condition. Randomization is structured so that there is equal representation of gender and minorities in both the Experimental and Control groups. Participants then meet with a clinical evaluator (C.E.), who completes the baseline assessments. After completion of the baseline assessment, the R.A. introduces participants to the appropriate intervention for their condition.

Participants in the Control condition are taken to a quiet room and shown the first of four videos (Teens and Tobacco, Tobacco and Human Physiology, Smoking and Human Physiology, and Butt Out). After the first video session, the R.A. schedules a time to meet for the next session to view the next video until all videos are completed. Participants are scheduled by the R.A. for follow-up assessment sessions with the C.E. at 30 days and 120 days post baseline assessment. After the final evaluation, control participants were invited to access the CD-ROM program if they wish.

Experimental participants undergo the same evaluation in the same manner as control participants. The R.A. introduces the computer and program to the student, explains how the program works, and assists the participant in coming up with a personal code to enter into the computer. The R.A. tells the participant that he/she would be available if there are problems with the computer, and then leaves the individual alone with the program. As with the Control condition, when the participant is done with one session, the R.A. schedules a time for the participant to return for subsequent sessions. Upon completion of the program, experimental participants will undergo a satisfaction interview, assessing the degree to which they found the program interesting and helpful. As with the control participants, experimental participants were scheduled for the same assessments 30 days and 120 days post baseline.

Visit the SBIR Product Directory online at http://cancercontrol.cancer.gov/hcirb/sbir

Turning Cancer Research into Commercial Products



At 30 days and 120 days post baseline, the R.A. schedules a meeting between the C.E. and participants for the follow-up interviews using the follow-up assessment package. In addition, for participants who claim on the tobacco-use questions to be abstinent, the C.E. consults a randomized schedule to see whether the participant will receive a cotinine test. Samples are stored frozen for later analysis and shipped in dry ice by overnight mail to the laboratory in batches. These procedures are identical for the 30-day and the 120-day follow-up process. Participants receive \$45 for each of two follow-up periods (totaling \$90) for the efficacy study.

Acceptance and Satisfaction Study: A short "exit survey" will be conducted in a face-to-face interview that asks three satisfaction questions rated on a likert scale, including, "How satisfied were you with the program overall?", "How likely would you be to recommend the program to a friend?" and "How much did the program help you address your tobacco use?" Additionally, the computer captures the number of sessions each participant begins, whether the session was completed or not, and the percentage of those who were exposed to the program for at least four sessions.

Outcome Measures

Measure 1: For both tobacco users and nonusers: knowledge about tobacco and its consequences (Knowledge Test)

Measure 2: For users only: quit rates, reduction rates, and the stage-of-change continuum (Stage-of-change adapted from Prochaska et al. 1994, Tobacco use interview questions adapted from Sussman et al. 1995, Fagerstrom Tolerance Adolescents Questionnaire adapted from Prokhorov et al. 1996, and biochemical validation via Cotinine testing.

Evaluation Methods

Computer assessment, paper questionnaires, electronic tracking of the extent and manner of Rebels program use, Biochemical testing for tobacco usage

Research Results

Efficacy: Results suggest that both interventions significantly improved knowledge (within subject effect) in both tobacco users and nonusers (overall F = 63.95, df = 1,210, p < .001), with no main effect of group (video or computer) or interaction. This same pattern of results was obtained for smokers and nonsmokers separately and there were no main effects for gender (57% of the sample was female) or race (38% of the sample was minority students). This pattern was repeated for quit rates (quitting claims were verified by Cotinine tests; smokers who did not complete the follow-up assessments were counted as still using). That is, at post intervention the video condition achieved a 14.8% quit rate, while Rebels produced 15%. At the three-month follow-up, the video quit rate was still 14.8% while the Rebels rate increased to 23.3%. The differences between conditions are not significant (although they both are significantly different from no change), and these rates compare well with literature reports of naturally occurring quit rates (0% to 11%; Sussman et al., 1998).

In addition to quit rates, self-reported reduction in tobacco use by those who continued to use was significant (F=7.22, df=1.59, p=.009) for both conditions, again with no group effect or interaction.

Turning Cancer Research into Commercial Products



Finally, for smoking students who completed all three assessment points, the percentage of students who increased at least one stage of readiness to change at post-intervention was 29.7% for Rebels and only 8.8% for video (Chi-square = 4.6, sig = .03). At the 3-month follow-up the percentages were 29.4% for Rebels and 24.3% for video.

Such findings suggest that the Rebels CD-ROM program is reasonably effective delivery system for tobacco use prevention and cessation interventions, but that Rebels did not produce effects markedly superior to the video control.

Satisfaction: High consistency among the satisfaction questions (coefficient alpha = .89) permitted responses to be combined for this analysis. On a scale from 1 "strongly disagree" (negative) to 7 "strongly agree" (positive) (note: negatively worded questions were reverse coded), the entire group achieved an average of 5.76, suggesting a high degree of satisfaction and acceptance. Results were similar for both genders and for minority students. Indeed, minority students (Mean rating = 6.0) rated the program significantly higher than white students (mean = 5.6).

Barriers & Solutions

Usability problems are evident in two major areas: (1) the technical requirements of the program, and (2) user comprehension and navigation through the program. The computers in the participating high schools turned out to be of extremely variable suitability. Some did not have speakers or sound cards, and some did not have up-to-date video cards or sufficient RAM memory to run a multimedia program smoothly. These problems were dealt with by upgrading school computers. We also ran into computer systems and network problems that interfered with the installation and smooth running of the program. These problems were particularly acute when multiple students attempted to print their "docupaks" (individualized printouts about tobacco risks and prevention/cessation strategies) and the printers were unable to handle multiple jobs. We dealt with printing problems by handing students photocopied versions of the printouts. At other times, conflicts between computers and the program caused crashes, which required rebooting. Unfortunately, these hardware and software incompatibilities resulted in program glitches that interfered with the smooth running of the program and may have diminished the potential impact of the program as designed. Through these challenges, we observed and documented these problems, recreated them at our offices, and then worked with our programmers to make corrections.

We redesigned the program for greater control over hardware and software contingencies, such as consolidating the program into fewer sessions and giving users more control over printer functions.

Certain design changes were necessary. The original idea, based on input from focus groups, was to allow users to explore a virtual 3D environment in an open-ended way. Once we were actually in a school environment, students did not have the patience for this type of design. In a structured, scheduled school environment where students have limited time, a linear philosophy is more realistic. Students need to get the information and complete required tasks because of competing demands at school. As a result, we removed a number of screens in the program, and this "tightening up" of navigational forced users into more linear paths. This permitted students to get to the relevant material rather than spend time with "irrelevant" features like trying to figure out which door to open.

The changes made to Rebels resulted in a shorter program, an elimination of program crashes, reduced confusion about navigation, and more accurate responses to program tasks.

Product(s) Developed from This Research

Rebels: The Battle for a Smoke-free Future